UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION	**CIVIL ACTION NUMBER: 19-md-02875**
	DISCOVERY CONFERENCE VIA ZOOM

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
September 26, 2023
Commencing at 4:02 p.m.

B E F O R E: **THE HONORABLE THOMAS I. VANASKIE (RET.)**
SPECIAL MASTER

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Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

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Judicial Law Clerk to The Honorable Robert B. Kugler

Larry MacStravic, Courtroom Deputy

(PROCEEDINGS held via Zoom before SPECIAL MASTER THOMAS I. VANASKIE at 4:02 p.m.)

SPECIAL MASTER VANASKIE: I have the agenda.

We'll get started and Loretta can join us. Maybe that's her coming in now.

I have your agenda letters. It seems to me there's not a whole lot to be addressed today, but I've been surprised before. And from what I understand, there are two topics to be addressed today. Maybe there's more.

But the first topic has to do with the end date for discovery from Aurobindo, at least as I understand it.

Do I have that right?

MS. GOLDENBERG: Hi, Your Honor. It's Marlene Goldenberg. More or less, yes. It's actually the end date just for a discrete number of custodians, but that's right.

SPECIAL MASTER VANASKIE: Right. Okay. And, Kate, you flashed on my screen, so are you addressing this on the defense side?

MS. DEAL: Yes, Your Honor. Good afternoon.

SPECIAL MASTER VANASKIE: Good afternoon. So where do we stand with this? Marlene, I'll ask you first.

MS. GOLDENBERG: Sure. So I'll start with the good news.

The good news is we agree on who the custodians should be. We agree on everybody who is going to end in 2019,

and we've agreed on five of the custodial productions going up through the present. So where that leaves us is with eight custodians in dispute. And the eight that are left are listed in our agenda letter, minus three of them. And I can read those names into the record if you want or --

SPECIAL MASTER VANASKIE: Why don't you. I have your letter, but why don't you read them in.

MS. GOLDENBERG: Sure. Maybe just for the sake of completeness.

The five that we've agreed that should go through the present are Sirinivas K. Rama. And that's not highlighted in our agenda letter. That's in the defendants', though.

The next one is Ram Mohan A. Rao. Then we have Sudhakar Reddy Mandepudi, Jaipal Reddy, and Blessy Johns.

SPECIAL MASTER VANASKIE: Okay.

MS. GOLDENBERG: All right. So now we get to the eight disputed custodians. And we've had lots of meet and confers and have just reached an impasse on these.

But again, you know, we agree on who the custodians are, we agree that these are relevant people, so really the only question is should these custodial productions go through the present.

And in order to answer that question, I wanted to give Your Honor a little context for what was happening at Aurobindo between 2019 and now so you kind of understand why

Aurobindo has this number being proposed.

So as a reminder, Aurobindo manufactured irbesartan at two different units, unit 1 and unit 9. And on June 20, 2019, six months before Aurobindo wants to cut off the custodial productions for the eight custodians in dispute, the FDA sent Aurobindo a warning letter. And by the way, it was addressed to the first disputed custodia, Mr. Govindarajan.

I apologize if I didn't pronounce that correctly, but you'll see that he's the first one on our list.

And in the publicly available version of this letter, the FDA wrote that there were repeat observations at multiple sites, and they specific cite unit 1 and unit 9, again, where irbesartan was manufactured, as the facilities where they found repeat CGMP deficiencies. And they stated -- and I'm quoting now -- these facilities are also considered to be in an unacceptable state of compliance with regards to CGMP. These repeated failures at multiple sites demonstrate that management, oversight, and control over the manufacture of drugs are inadequate.

So after that, Aurobindo convened large teams of people to respond to this warning letter. And based on the documents that we have and what we can glean from the productions that have been made so far, the individuals on our list of disputed custodians were among the most important people who were involved in responding to this warning letter

and the 2019 warning letter that we're going to talk about in a minute.

So then we get to January 2022. And again, Aurobindo receives another warning letter, this one directed directly at unit 1 and again addressed to the same Mr. Govindarajan.

So this warning letter cited Aurobindo for a number of things, but most importantly it noted that Aurobindo failed to adequately inspect critical deviations and that it hadn't investigated things that had gone wrong very well.

So in other words, what went wrong with irbesartan is still being investigated, and the investigation continued long past the proposed December 2019 date for these custodians.

So I wanted to just point out one other thing. There is a response to this warning letter that was produced to us, and I didn't attach it to our agenda letter because it's more than 2,400 pages long. But to save you some time, the CliffsNotes version of this document is that Dr. Rao is responding to the FDA's warning letter, and he's writing to the FDA to tell the FDA all the things that Aurobindo has been doing to remedy these irbesartan issues. And not just remedy them, investigate them. So in other words, the investigation is still ongoing.

And just to give you a sample of how much they're still discussing irbesartan at this point in time, the word "irbesartan" appears in this document 1,791 times. The word

"nitrosamine" appears 742 times. So suffice it to say, this is still very much an ongoing investigation at Aurobindo during this time period. And because these ongoing investigations have continued, we've asked that these custodians be added to the list.

SPECIAL MASTER VANASKIE: All right. Thank you very much.

All right. Kate?

MS. DEAL: Good afternoon, Your Honor.

So as we get into some of the specifics and address some of the comments made by counsel, Your Honor, I just want to note at the outset that we don't raise a discovery dispute with the Court lightly. You haven't heard from us. And I think you can tell by our letter to the Court last week, we have been accommodating to the point of being conciliatory in irbesartan discovery negotiations with plaintiffs, probably to a fault.

The more we've given, the more plaintiffs have demanded. The goalposts keep moving out and expanding with each concession we make. So we're now in a position where we really believe that if these core concepts of relevance and proportionality that are in the rules actually apply, we've reached that point here.

And so, you know, to better understand that and the context in which this dispute arises, we really do need to

level set about the scope of plaintiffs' actual irbesartan claims against Aurobindo. By any measure, Your Honor, those claims are incredibly narrow, and the incredibly narrow scope of those claims dictates the appropriate scope of discovery under the rules.

As Your Honor may be aware, Aurobindo is not a defendant in losartan. That's not at issue. And there's no claims in this case against Aurobindo related to its finished dose irbesartan. Instead, the plaintiffs' economic claims here pertain to a very small quantity of Aurobindo's irbesartan API. And that API that forms the basis of their claims was manufactured using a particular process in 2016 and 2017 and resulted in a recall in 2018 due to the alleged presence of NDEA. Aurobindo completed that recall in late 2018.

To give you a sense of the scope here, the total dollar value of Aurobindo's net sales of the entirety of that recalled API is approximately $200,000 in the aggregate.

With respect to personal injury claims against Aurobindo pertaining to that irbesartan API, there really aren't any, Your Honor. We've confirmed with plaintiffs' lead counsel that there appears to be only one single person in the entire MDL who claims any injury whatsoever from Aurobindo's irbesartan API that was recalled and that forms the basis of the claims in the MDL.

And so it's against this backdrop of this incredibly narrow scope of claims against Aurobindo in the irbesartan litigation that we have to evaluate the continually expanding requests for custodial discovery.

To date, Aurobindo has agreed to produce custodial data using very broad search terms for 22 custodians despite that narrow scope of claims across a six-year period, from 2013 -- which, by the way, the plaintiffs expanded the start date of custodial discovery for irbesartan by a year from irbesartan core discovery. We thought that was not warranted, but we agreed to it. And we are agreeing to produce 22 custodians' documents through December 2019, which extends a year past the completion of irbesartan -- of Aurobindo's irbesartan API recall that forms the basis of plaintiffs' claims. Just completing that custodial discovery, Your Honor, will exceed the total value of plaintiffs' pleaded claims against Aurobindo in the irbesartan MDL here.

As I mentioned -- as I may have mentioned, plaintiffs have already doubled the number of custodians we proposed. They extended the start date a year earlier than governed core discovery. They expanded the scope of the search terms that we tried to tailor to the actual claims here. And after all of that, Aurobindo agreed to custodial discovery for these 22 custodians over a six-year period through 2019. And then after that, plaintiffs are now demanding four additional years

of custodial discovery from 13 custodians.

We think that's unjustified and improper for several reasons. First, it's inconsistent with their own document requests, which set an end date of December 2019. It's also inconsistent with the approach to custodial end dates taken in valsartan, where our custodial productions extended a year post recall, not five years post recall as plaintiffs now suggest is appropriate here. A year post recall is December 2019 for Aurobindo in the irbesartan litigation.

Plaintiffs' latest proposal also disproportionately increases the existing collection and production of what is already terabytes of custodial data and millions of documents to be produced -- to review for production by an additional 40 percent.

And all of this pertains to information that is largely untethered to plaintiffs' irbesartan-related claims to Aurobindo.

I want to point out, Your Honor, that plaintiffs' rationale for this multi-year expansion of custodial data is that they want to see internal communications about FDA communications that post-date Aurobindo's irbesartan API recall by up to five years.

But let me be super clear about this. Plaintiffs will already receive all of the FDA communications, everything FDA sends to Aurobindo and everything that Aurobindo sent

back, through May 22nd of 2023. And, by the way, they already have most of them. We produced all of that through September 2022 when we made our core discovery productions.

Plaintiffs can make whatever arguments they wish to make about the contents of those documents. They know what the FDA inquired about after 2019, and they know the company's responses in full. As counsel just noted, we've produced thousands of pages about those regulatory inquiries. There is simply no basis for broad custodial discovery from Aurobindo into internal communications about regulatory communications. And, quite frankly, plaintiffs have never articulated one.

And it's certainly hard to do, because the additional custodial discovery they seek pertains to manufacturing from an entirely different time period than is at issue on the claims they pleaded here. It pertains to a different manufacturing process than those at issue here because that changed post recall. And perhaps most importantly, the additional communications about these regulatory communications don't involve any alleged nitrosamine impurities in Aurobindo's irbesartan API. The issues that are raised in the 2022 warning letter didn't result in API -- didn't result in nitrosamine contamination. There is no claim in this case about that. It didn't happen.

So for all of these reasons, Your Honor, the latest request -- (technological interruption) -- by four additional

years, five years post-recall, in this incredibly broad fashion to us seems like a fishing expedition.

If plaintiffs have their way, we are embarking on a literal decade of vast custodial discovery from 2013 to 2023 that all pertains to $200,000 of irbesartan API sales that occurred in 2016 and 2017. That is disproportionate on its face and borders on absurd.

Nevertheless, Your Honor, given all of this, we don't think plaintiffs are entitled to any more custodial data. But we compromise. In yet another effort to meet them in a spirit of compromise, we offered five custodians, five additional custodians, for four additional years up to five years post-recall.

We explained to counsel their roles and why we thought they were the folks who had primary responsibility for any ongoing regulatory communications, because -- that plaintiffs already have. It includes the only US regulatory custodian on plaintiffs' list. It includes Dr. Rao, who was the primary person responding to the subsequent regulatory inquiries. It includes three other individuals who we think had the most robust involvement in these issues that we think have tangential relevance to the actual claims in this MDL.

So for all of these reasons, Judge Vanaskie, we think that what we've proposed is more than reasonable. It's certainly more than proportional in light of the narrow scope

of the claims here. And it's also reasonable and proportional given the already expansive custodial discovery we've agreed to, in light of the costs and the burden associated with it, in light of the fact that plaintiffs have all of the FDA communications back and forth through May of 2023, and in light of the fact that all of the regulatory issues identified by plaintiffs' counsel that pertain to 2016 through 2019 are already covered by the 22 custodians we've agreed to produce.

THE COURT: All right. Thank you.

Ms. Goldenberg, Marlene, do you want to address the proportionality concern that has been raised here?

MS. GOLDENBERG: Happy to, Your Honor. And I can do it in two points.

First of all, I'll say we disagree on the value of the case. We have economic class cases. We have a medical monitoring class, and the value of that, at least according to our internal calculations -- which I don't want to read into the record because I'm getting different numbers from people behind the scenes -- but I'll say that they are vastly different.

I can secondly say that this isn't really out of line in comparison to what other defendants have agreed to do. So, for example, ZHP has 80 custodians. You'll see that Vivimed has a number of custodians, and they agreed to bring everybody up a year past the production date, which is a pretty

comparative or comparable ask to what we're doing with half of the custodians that we agreed upon with Aurobindo.

And there are a lot of ongoing issues that Aurobindo has that other defendants don't. Other defendants either had factories close earlier, like Teva, or didn't have ongoing warning letters, and the other defendants who do have warning letters that have continued either are still negotiating or have agreed to produce more.

But in Aurobindo's case especially, they are being told directly by the FDA that their investigation isn't done. And, you know, we have a burden of proof at trial that we have to meet to show exactly what went wrong here. And if the FDA is telling Aurobindo you're not getting this right yet, then we have to be able to show that we have the documents that explain exactly what did go wrong. So, you know, there are lots of things still at play here that would justify these documents being produced.

SPECIAL MASTER VANASKIE: All right. Ms. Deal, would you address the question about the FDA findings and the indication that their investigation is not yet complete.

MS. DEAL: Yes, Your Honor.

So the FDA -- excuse me, 2022 letter from FDA is not about any irbesartan API that was manufactured in 2016 or 2017 or that was recalled in 2018. It's different manufacturing, post-recall, using a different manufacturing process that

changed post-recall.

The letter identifies two issues. One is about the acceptable ammonia limit and whether the company needs to do additional testing to investigate the additional ammonia limit in a starting material that it had proposed, and the other deals with a process issue pertaining to method transfer. And, again, the FDA says, we need you to do more testing. But none of it pertains to the actual irbesartan API that was purchased by any claimant in this MDL, not at the same time period, not using the same manufacturing process. And, by the way, neither of those issues in the 2022 letter from FDA resulted in alleged nitrosamine contamination of any irbesartan API at any time, much less at the time period that governs the plaintiffs' claims here.

And so again, Your Honor, what's going on five years post-recall and seven years post-manufacture and sale of the API that forms the basis of plaintiffs' claims here is not tethered to what they need to prove in any trial. But, nevertheless, we've given all of them -- we've given them all of those regulatory documents, and they can say whatever it is they want to say about what happens five, six, seven years after the fact. But it doesn't pertain to the irbesartan API that their clients purchased or consumed, because it's different time periods, it's different manufacturing, and none of those subsequent issues related to a recall or any alleged

nitrosamine contamination in irbesartan API.

SPECIAL MASTER VANASKIE: Ms. Goldenberg, do you want to respond to that? I mean, I'm being told that this really doesn't deal with the product that's at issue here.

MS. GOLDENBERG: Yes, Your Honor.

So the document that I gave you the CliffsNotes from earlier -- and just for the record, the Bates number on that is APL-MDL-28752983378. Again, that's a February 3, 2022 letter dated -- or sent from Aurobindo back to the FDA. That's the document that mentions or -- that mentions irbesartan over 1,700 times and that mentions nitrosamines, I think -- I don't have the figure in front of me, but hundreds -- 742 times again.

They're very much discussing their manufacturer and their investigation of the nitrosamine problem with the FDA in response to this letter.

Now, I do agree with Ms. Deal that the letter didn't call out irbesartan by name, but the response and the discussion that occurred with the FDA in response to that letter very much did.

And I should note too that the 2019 letter that we didn't hear Ms. Deal talk about is very much about irbesartan and the issues that occurred. And that went on long after December 2019 as well, especially with the FDA and Aurobindo both acknowledging that the problems in the 2022 letter were

similar to the CGMP issues that were addressed in the 2019 letter.

SPECIAL MASTER VANASKIE: Is there -- go ahead, Ms. Deal, if you wanted to say something.

MS. DEAL: Yes. So just on that last point, Your Honor.

I just want everyone to remember that 2019 is within the time period we've agreed to. And so we are producing full custodial data for 22 custodians during that time period, and we also -- I think everyone reached an agreement with plaintiffs that if there is evidence that there is a discussion that is relevant, that is ongoing at the end of 2019, plaintiffs can come back and request additional information to finish that thread. So that is already covered and agreed to.

What's at issue here is what's going on in 2022, which, again, as I've already explained, is truly, you know, more remote and untethered to the actual irbesartan API and the 2018 recall that is the basis of plaintiffs' pleading here.

And the other thing I just want to point out, Your Honor, is plaintiffs have all of that information. What they're asking for is custodial discovery for communications -- internal communications about those regulatory communications, which is even another step removed

from anything relevant here, when they have the full back and forth with the regulator. And so they're going to find some hidden gem in some internal communication that says, what about the irbesartan that was sold seven years earlier and recalled five years earlier. I mean, it truly is tangential.

And what we're agreeing to do in giving them all of the regulatory communications plus four additional years of custodial data for the five employees who have -- who we think have the most involvement in those activities is, you know, I think beyond generous and certainly beyond proportional to the needs of the case.

SPECIAL MASTER VANASKIE: Ms. Goldenberg.

MS. GOLDENBERG: Yes. One quick response on that, Your Honor.

You heard Ms. Deal mention that our deal was that if we found ongoing discussions that needed to be completed, we would raise them. And I suppose I could have waited until all of their documents poured in to do that, but why do that when I already know that they're incomplete now?

So, you know, all this is going to do if we go with Aurobindo's plan is kick the can down the road, and we're going to be back here right after they produce documents, saying, hey, Judge, they truncated their production in 2019. We know this warning letter went out six months before the custodial production ended. We're back because we don't have

it all and we knew we didn't have it all last time.

And the internal communications aren't something that we should brush aside as if they're not a big deal. These are all of the documents that are the building blocks to what goes out to the FDA, but we're going to get the internal test results. We're going to see where the deficiencies were, we're going to see the changes in the policies that showed how things slipped through the cracks before. These are the explanations for how this contamination happened.

And I haven't seen anybody try to argue that these aren't relevant in another context. This is just Aurobindo's attempt to say that we don't need it because it seems like they don't want to do the work to produce it. But this is very relevant at any time, including here.

MS. DEAL: Your Honor, believe me, we can be accused of a lot of things, but not doing enough work, given the claims that are leveled against our client, is truly not one of them, when we are offering 22 custodians for a six-year time period plus five additional custodians for an additional four-year time period to span an entire decade of custodial discovery about claims that amount -- that relate to our client's sale of $200,000 worth of API in a one- to two-year period.

And so, again, they haven't articulated a reason why they need eight more, and, in fact, the reasons we got for the

additional eight I think I have factual errors and inconsistencies in them, and we've offered to confer about that them. But, again, the five people we're offering gives them everything that they're even asking for even if we think it is unreasonable.

And so -- and the other point I'll just respond to is we haven't done the custodial productions through 2019 because we're still spinning up backup tapes to pull out the six years worth of data that they're requesting for 22 people who in large part were not valsartan custodians. And so the notion that she's predicting the tea leaves that what we produced through 2019 is going to be deficient and warrant custodial data from 13 people through an additional four-year period is just made up. Right? It's not factually -- factually based in any production we've made or in anything that they've seen from any existing custodian to date.

SPECIAL MASTER VANASKIE: Why don't we proceed on that type of iterative basis, where you get the additional discovery from these five custodians up through May of 2023, see what is produced, and then if you have reason to believe that there's more, you come back.

Why is that not an appropriate approach?

MS. GOLDENBERG: We can do that, Your Honor, if that's your preference.

I would say that I do have specific reasons for why

we want each of these individuals, and there's nothing made up about our ask. I mean, I just read to you from a 2022 letter well outside of the time frame they're giving us documents for where they submitted 2,400 pages of material to the FDA on what they'd been doing since 2019.

But at a minimum, you know, I would think that we would get the regulatory affairs person over in India, Dasarathi, who's copied on pretty much -- at least in valsartan and my understanding is he had equal involvement with irbesartan, all of the regulatory issues. And then Mr. Govin -- oh, gosh. Govindarajan, who is the recipient of both FDA warning letters later on, we know for a fact that he was getting things beyond that point. And that falls directly in line with what Ms. Deal said that they should be producing to us anyway, which are all the regulatory documents.

MS. DEAL: Yes, Your Honor. They'll have all the regulatory documents. The question is, you know, what's a relevant and proportional number of custodial files to search given that they do have all of the regulatory responses. We've pitched the people who we think have the most primary responsibility there, and the hunch that somebody who was involved in valsartan must have been involved years later in a different drug with different issues is just not a valid assumption. And so, again, Your Honor, we're just picking names in a vacuum. And we're doing it without any regard to

burden or proportionality, because, again, what is happening in 2022 is not about the irbesartan that was manufactured and sold in 2016 and 2017 and recalled in 2018.

SPECIAL MASTER VANASKIE: It seems to me that at least the individuals that were just mentioned to me are not being pulled out of a hat or not selected at random, that there's a rational basis for suggesting that they're the kinds of persons or they have the kinds of positions that one would expect they would have relevant documents, relevant information. I'm talking about -- now about Mr. Govindarajan and the other -- I didn't get the name of the other person.

MS. DEAL: Yes. So, Your Honor, I think -- I mean, I'm going to butcher the names too.

I think the warning letters were sent to an individual, but he wasn't the one who signed the responses or sent the responses. We picked the people who were more substantively involved in that, because we assumed that that made more sense. We're happy to switch somebody out if that's what they want to do.

The other person, Dasarathi. This is an issue where I think plaintiffs have pulled him out based on a document they cite, but that document pertains to an entirely different production unit and pertains to an entirely different drug than what's going on with irbesartan at this time period.

SPECIAL MASTER VANASKIE: He's identified as the head

of regulatory affairs?

MS. DEAL: For corporate API, which is overseas. The reference that counsel gave to me, though, was a document where -- that relates to a different production unit altogether, unit 11. And it pertains to valsartan and not irbesartan.

And so our proposed custodians include the US head of regulatory affairs who is the person through whom all of the communications with the FDA go. And then we also produced the, you know, chief quality officer, Dr. Rao. He clearly is involved and is the one who signs all of the responses. And then we picked people at the relevant units who we thought had primary responsibility for the two issues that are in the 2022 letter, plus a third custodian who appears to have more robust involvement.

If we want to trade some out because plaintiffs prefer others than those, I mean, we're happy to have that conversation, but we shouldn't just be adding people, you know, based on information that doesn't appear to be, you know, one, proportional, or, two, targeted to the custodial data that plaintiffs now claim is particularly relevant and that we dispute.

SPECIAL MASTER VANASKIE: It does appear to me that Mr. Govindarajan would be a person expected to have relevant information, not drawn out of a hat. And I would suggest that

he be added to the list of five persons, so now make it six, not to substitute him for another person.

And then Mr. Dasarathi, why would he be relevant, Ms. Goldenberg?

MS. GOLDENBERG: Your Honor, he is, as Ms. Deal said, the head of regulatory overseas. And I think perhaps she, you know, was splitting hairs a little bit when she said the one document that I was referring to in a previous email to her referred to unit 11.

My understanding from seeing lots of documents with his name on it is that he's copied on all of the regulatory issues that occurred over in India. And I'll tell you, I mean, I'm happy to go through them today. I've got reasons and documents cited for every single custodian we asked for. There are people on this list who were at the FDA closeout meetings for warning letters. There's a guy who greeted the FDA inspectors when they first showed up.

I mean, these are not random people. These are all people who are highly relevant to the FDA warning letter, not just in '22 but also in 2019, who -- you know, where that issue certainly went beyond the end of that calendar year.

MS. DEAL: Your Honor, I'll say, you know, the notion that somebody is copied on something, we don't need everybody who's copied on every email. Right? We don't need duplicative custodial discovery because, remember, what we're

talking about is pulling all of the custodial files for all of these people who end up as custodians for a four-year period using -- we had proposed tailored search terms. Plaintiffs rejected it. Using all of the search terms related to all irbesartan discovery issues that are in 26 pages and hundreds of different iterations.

And so adding people because they're copied on the same emails that the person we proposed actually sent and authored creates -- you know, it seems like it's not a big deal, but it does create an exponentially, you know, larger burden for no added benefit, because you're going to get those communications from the actual author of them.

MS. GOLDENBERG: I mean, I disagree with that characterization of who these custodians are. And, again, Your Honor, I mean, these are like the core people that were involved in these inspections. And I'm happy to either go through them today or submit additional materials on why these people are relevant, but I can assure you that they're all here for a reason.

SPECIAL MASTER VANASKIE: Well, I have no doubt about that, but I also know that you have to put some reasonable limits on discovery as well, even in a case of this magnitude.

I'm going to add two custodians to the five that are going to be searched. I'm going to add -- I'll butcher the names -- Mr. Govindarajan and Mr. -- I'm assuming it's a

Mr. -- Dasarathi. Add those two, conduct the search. You can come back later if you think now there are gaps or information has been produced that suggests that one of the other six -- I guess there will be six that you're not getting custodial files on through the May 2023 date. You can come back and make a showing that it's likely they would have relevant information, the production of which would be proportional to the needs of this case. And that's how we'll proceed. All right?

MS. GOLDENBERG: Understood. Thanks, Your Honor.

MS. DEAL: Thank you, Your Honor.

SPECIAL MASTER VANASKIE: All right. Next issue? We have an issue with respect to wholesaler discovery?

MR. STANOCH: Your Honor, this is David Stanoch for plaintiffs. I don't really think there's anything per se for an issue for Your Honor to decide today.

Our inserts on the retailers and wholesalers are really by way of updates since there's been so many moving parts and it's commanded so much of Your Honor's attention in the last few weeks. We just wanted to let you know where we are.

We noted a few things with wholesalers that were giving us a little concern, but, frankly, given all the moving parts, Judge, and where we are, I don't think there's anything for you to decide today. And if -- and we can come back, you

know, in two weeks if there's something. That would be my view.

SPECIAL MASTER VANASKIE: Yes. I thought -- my recollection is that you were proposing to address this at the October 4 conference.

MR. STANOCH: Potentially, yes, Judge. And I'm sure Mr. Geoppinger will speak for the wholesalers, but we received a proposed schedule from them yesterday evening, which we're still going through. And we're not immune to the reality, Your Honor, that even under their proposed schedule, some of this may shake out by a matter of eight days or so, it looks like. So I'm optimistic that even if we have a theoretical dispute, that it may not be worth everyone's effort, the parties and the Court, even for the next CMC, when it might shake out anyway in a matter of days from that date.

SPECIAL MASTER VANASKIE: Okay. Very well.

Is Mr. Geoppinger on the line? Did he want to --

MR. GEOPPINGER: Good afternoon, Your Honor, I am. And if there's nothing to argue about, I'm not going to volunteer to argue, so...

SPECIAL MASTER VANASKIE: Good. There's nothing to argue about.

Is there anything else for today?

Ms. Goldenberg, Ms. Deal, do you need anything more from me on this issue?

MS. GOLDENBERG: No, Your Honor. I think we've got our marching orders. Appreciate you calling balls and strikes for us today.

MS. DEAL: Thank you, Your Honor.

SPECIAL MASTER VANASKIE: Thank you very much. It was well presented.

Mr. Harkins, did you want to be heard on anything?

MR. HARKINS: No, Your Honor. Just noting no other issues I'm aware of for the defense.

SPECIAL MASTER VANASKIE: All right. Very well. Then we'll adjourn for today. And see you again soon.

Thank you all very much.

(Proceedings concluded at 4:40 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Ann Marie Mitchell *28th day of September, 2023*
Court Reporter/Transcriber *Date*